

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

THE CITY OF HUNTINGTON,  
Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION, *et al.*  
Defendants

Civil Action No. 3:17-01362

CABELL COUNTY COMMISSION,  
Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION, *et al.*  
Defendants

Consolidated Case:  
Civil Action No. 3:17-cv-01665

**PLAINTIFFS' RESPONSE IN OPPOSITION TO MCKESSON'S MOTION FOR JUDGMENT UNDER  
RULE 52(C)**

July 25, 2021

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### PRELIMINARY STATEMENT

McKesson's Motion for Judgment on Partial Findings Regarding Actionable Conduct asks the Court to enter judgment against the Plaintiffs on the grounds that Plaintiffs cannot establish "actionable conduct."<sup>1</sup> McKesson's motion necessarily fails for several reasons. As a preliminary matter, McKesson's motion applies the incorrect legal standard and misconstrues the conduct underlying Plaintiffs' claims for public nuisance. Moreover, McKesson ignores the extensive documentary and testimonial evidence in the record demonstrating its unreasonable and unlawful conduct.

Plaintiffs' evidence overwhelmingly demonstrates that McKesson behaved unreasonably in its distribution of prescription opioids, thus providing the predicate culpable conduct for finding of public nuisance. Given the dangerous and addictive nature of these drugs, it was necessary for McKesson to control their distribution and to take steps to prevent diversion for illegitimate purposes. McKesson created national policies that purported to provide tools to prevent diversion. But these tools were not, in fact, effective in preventing diversion and McKesson did not, in any event, seriously implement them. Its failure to control the supply chain for the dangerous drugs it was distributing was unreasonable and created a public nuisance, when inevitably and predictably, the drugs were diverted. In particular, the evidence shows that McKesson's distribution of prescription opioids was unreasonable because:

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<sup>1</sup> This response addresses the second argument in McKesson's motion relating to actionable conduct. *See* Doc. 1449 at pp. 15-38. McKesson's arguments relating to causation (including McKesson's allegedly de minimis market share) are addressed in Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation, Doc. 1469. Additionally, McKesson made no attempt to allocate responsibility to others, either by showing that the public nuisance it is a proximate cause of is capable of being allocated, or by showing a reasonable basis for such an allocation, elements for which it had the burden of proof. *See* Plaintiffs' Consolidated Response to Defendants' Motions for Judgment Re: Abatement, Doc. 1470 at pp. 31-35.

- McKesson’s program for detecting “suspicious orders” of prescription opioids was not designed to, and could not, detect a meaningful percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion;
- McKesson failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed indicia of diversion;
- McKesson failed to properly implement the suspicious order monitoring (SOMs) program that it did have;
- McKesson knew that its anti-diversion programs were inadequate, and knew the devastating effects of the failure to maintain controls against diversion, but failed to make changes to address the inadequacies;
- McKesson’s failure to detect, investigate, and halt suspicious orders violated the federal Controlled Substances Act (“CSA”), which sets the standard of care for reasonable conduct in the distribution of dangerous narcotics.

This evidence is sufficient to establish McKesson’s culpable conduct, and under West Virginia law, liability for public nuisance.

#### **RULE 52(C) LEGAL STANDARD**

Plaintiffs incorporate the Legal Standard as set forth in Plaintiffs’ Memorandum of Law in Opposition to Defendants’ Motions for Judgment on Partial Findings on Causation.

#### **THE EVIDENCE**

##### **I. MCKESSON’S NATIONAL POLICIES WERE NOT DESIGNED TO, AND COULD NOT, DETECT MEANINGFUL QUANTITIES OF SUSPICIOUS ORDERS**

The evidence introduced at trial shows that, throughout the time period at issue in this case, McKesson lacked policies that were capable of detecting significant numbers of orders with indicia of diversion – that, is, those that were suspicious because of their size, volume, or frequency. This was true of the policies that McKesson maintained before 2007, it was also true of the later policies that McKesson implemented beginning in 2007.

**A. MCKESSON’S PRE-2007 ANTI-DIVERSION POLICIES WERE INADEQUATE TO DETECT SUSPICIOUS ORDERS**

From at least 1997 until May 2007, McKesson did not have a system for monitoring, identifying and reporting suspicious orders of controlled substances. For example, if a customer’s previous twelve-month average was 1,000 pills, a pharmacy could order 3,000 pills the next month before McKesson’s system would even flag it as an excessive order.<sup>2</sup> The system that was in place, found in Section 55 of the McKesson Drug Operations Manual, consisted of voluminous retrospective reports (referred to as “DU-45s”) which flagged all customers whose sales exceeded three times the customer’s monthly average for that drug code.<sup>3</sup>

McKesson’s three times threshold to flag an order was so high that it was unable to detect gradual increases in diversion. The system did not consider the frequency or pattern of orders that should have allowed it to make informed decisions to investigate and cancel certain shipments to its pharmacy customers that the governing regulations defined as suspicious.<sup>4</sup>

The SOMs system had other flaws. During a January 2006 meeting with DEA, McKesson revealed that one of the reasons it had failed to realize the full volume of hydrocodone it was shipping to pharmacies was because its suspicious order monitoring program was only tracking the sale of branded opioids and excluded generics.<sup>5</sup> McKesson’s failure to monitor the sale of

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<sup>2</sup> Gary Hilliard 1/10/19 Depo. at 167:2-167:11, 167:15-167:21.

<sup>3</sup>MC-WV-00451 at 00046; Gary Hilliard, 1/10/19 Depo. at 163-169. McKesson’s own employees also acknowledged that DU-45 reports did not satisfy McKesson’s regulatory obligations and were instead of limited utility. Gary Boggs, Vice President of Regulatory Affairs and Compliance at McKesson, testified that submitting a report of sales that went over a particular threshold, without evidence of due diligence, does not satisfy McKesson’s obligations under the Controlled Substances Act. Boggs Depo. at 291-291. During trial, Mr. Rannazzisi testified that excessive order reports were not useful to DEA. 6/8 Trial Tr. (Rannazzisi) at 110-111.

<sup>4</sup> See 21 CFR 1301.74(b).

<sup>5</sup> P-00051.

generic controlled substances drugs was a “systemic failure” that was not limited to any one distribution center.<sup>6</sup> This means that, prior to 2007, McKesson was not monitoring the sale of generic opioids into Cabell/Huntington.

McKesson’s pre-2007 SOMs policies were so inadequate that, in August 2006, DEA issued an Order to Show Cause to McKesson’s Lakeland Distribution Center for violations of the Controlled Substances Act in connection with its sales to internet pharmacies.<sup>7</sup> McKesson’s flawed system resulted in shipments of 3.5 million hydrocodone pills to one of these pharmacies – an amount that was **nearly 150 times more** than the national average.<sup>8</sup> The violations were not unique to McKesson’s Lakeland facility. On November 1, 2007, the DEA issued a second Order to Show Cause to McKesson’s Landover, Maryland distribution facility.<sup>9</sup> At the same time, at least four other distribution centers were also under investigation by the DEA.<sup>10</sup>

**B. MCKESSON’S MODIFIED 2007-2008 ANTI-DIVERSION POLICIES  
REMAINED INADEQUATE TO DETECT SUSPICIOUS ORDERS**

In April 2007, McKesson attempted to resolve the Lakeland Order to Show Cause by writing the DEA a letter describing its plans to implement a new compliance program as of May 1, 2007 that would be implemented across all of its distribution centers.<sup>11</sup> This “improved” program, which McKesson called the Lifestyle Drug Monitoring Program (“LDMP”).<sup>12</sup> Contrary

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<sup>6</sup> 6/8 Trial Tr. (Rannazzisi) at 18-18; 20; 40; Hilliard, 1/10/19 Depo at 122-123.

<sup>7</sup> P-23733; P-00016.

<sup>8</sup> P-00016.

<sup>9</sup> P-00016 at 00188; 00202.

<sup>10</sup> P-00016 at 00188; 00202.

<sup>11</sup> P-23845.

<sup>12</sup> P-00098.

to the descriptions of the LDMP McKesson provided to the DEA,<sup>13</sup> there were numerous shortcomings in the LDMP's design and implementation.

The LDMP was limited to four drugs: oxycodone, hydrocodone, alprazolam, and phentermine. It did not monitor any other controlled substances. For these four drugs, an 8,000 monthly dosage unit threshold was set for every McKesson customer nationwide.<sup>14</sup> Not only did the LDMP not apply to all controlled substances, but it also only applied to certain pharmacy customers. Specifically, the LDMP only monitored the purchases of independent pharmacy customers and was never used to track the purchases made by retail national account customers such as Rite Aid.<sup>15</sup> Notably, more than a year after McKesson told the DEA it had failed to track the sale of generic drugs, an internal audit noted that the LDMP may not be tracking all generic controlled substances.<sup>16</sup>

While the LDMP was national in scope and supposedly in place in all distribution centers, an audit of the Washington Courthouse Distribution Center – the distribution center primarily responsible for shipments to Cabell/Huntington identified significant concerns with the program. For example, one observation noted that “Regulatory Affairs does not provide structured training to Distribution Center personnel or other functions that provide input to the DEA process,” acknowledged that “[c]ompliance regulations are not reinforced or periodically revisited,” and highlighted the fact that account managers for its retail national accounts (“RNAs”) such as Rite Aid were not following LDMP procedures.<sup>17</sup>

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<sup>13</sup> DEF-WV-01527 at 00001, 00002.

<sup>14</sup> P-00098.

<sup>15</sup> P-00098, P-12937, P-12938.

<sup>16</sup> *Id.* at 0002.

<sup>17</sup> *Id.*

McKesson's internal audits of the LDMP identified several instances in which customers whose purchases exceeded 8,000 doses "would be missed by the current process."<sup>18</sup> For example, purchases were calculated according to distribution center, a customer could exceed the monthly 8,000 dosage unit threshold and avoid detection by spreading its purchases across multiple distribution centers.<sup>19</sup> Similarly, customers with multiple accounts at a single distribution center could also be missed.<sup>20</sup>

Another internal audit of the LDMP program dated August 23, 2007 indicated that the monitoring appeared to be "after the fact" and "should be initiated sooner."<sup>21</sup> Although the LDMP identified orders that exceeded an 8,000 dosage unit threshold, this threshold was only a soft cap: rather than automatically blocking orders that exceeded the threshold. The LDMP merely prompted an investigation into the sale.<sup>22</sup>

As Director of Regulatory Affairs Gary Hilliard acknowledged, the LDMP had no mechanism to block orders once the 8,000-unit threshold was met or while an investigation was ongoing.<sup>23</sup> As a result, pharmacy customers could exceed the 8,000 monthly dosage thresholds prior to a due diligence review being completed by McKesson.

One such example was Sav-Rite Pharmacy in Kermit, West Virginia.<sup>24</sup> During the period of time that McKesson's LDMP program would have been in effect, McKesson shipped an average

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<sup>18</sup> Id.

<sup>19</sup> Id.

<sup>20</sup> Id.

<sup>21</sup> P-12938 at 00003.

<sup>22</sup> 5/24 Trial Tr. (Oriente) at 35; Hilliard 1/10/19 Depo at 63-13.

<sup>23</sup> Hilliard 1/10/19 Depo at 63, 241-241, 241-241.

<sup>24</sup> P-44759

of more than 300,000 dosage units of hydrocodone to Sav-Rite – approximately **36X** more than the 8,000 dosage unit threshold.<sup>25</sup>

McKesson even went so far as to set up a call center in Texas called “ServiceFirst” where between 80 to 100 customer service employees made “proactive” calls to McKesson’s customers to “ask if they wanted an increase.”<sup>26</sup>

The LDMP and its predecessors were so ineffective that the DEA was forced to intervene. On May 2, 2008 McKesson entered into an Administrative Memorandum of Agreement (“2008 Agreement”) with the DEA that confirms its lack of CSA compliance.<sup>27</sup>

**C. MCKESSON’S 2008 CONTROLLED SUBSTANCES MONITORING PROGRAM “CSMP” REMAINED INADEQUATE TO DETECT SUSPICIOUS ORDERS.**

Following the 2008 Agreement with the DEA,<sup>28</sup> McKesson once again launched a new, national monitoring program called the Controlled Substances Monitoring Program (“CSMP”). McKesson, however, undermined the CSMP’s effectiveness by setting its customers’ thresholds unreasonably high, warning customers who were approaching their threshold limits, or, in many cases, simply ignoring the policies set forth in the CSMP altogether.

McKesson’s CSMP set thresholds too high, especially for some of its national RNA customers like Rite Aid. Under the CSMP, thresholds for customers generally were set by taking the highest ordering month from prior 12 months and adding a 10% buffer, but, Rite Aid received a 30% buffer.<sup>29</sup> In addition, the thresholds were set based on purchases from the prior twelve

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<sup>25</sup> P-44759

<sup>26</sup> Gustin Depo 8/17/2018 at 330:6-339:22.

<sup>27</sup> See Evidence § V.A.4, *infra*.

<sup>28</sup> See Argument § VI.A.

<sup>29</sup> 5/24 Trial Tr. (Oriente) at 129; P-08309; P-08247; P-13211; P-13212.

months, a period in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies. And, like McKesson's predecessor systems, the CSMP did not consider the frequency or pattern of orders.

McKesson also took affirmative steps to reduce the number of flagged orders by warning customers that they were approaching the threshold. Threshold warnings were provided to customers to prevent order blocks and lost sales.<sup>30</sup> McKesson continued issuing threshold warnings to customers for five years until finally abandoning the concept in 2013.<sup>31</sup> This process ensured that customers could seek an increase before McKesson would be forced to block their orders. In fact, the threshold warning systems were designed solely to ensure that thresholds could be increased before any sales were lost.<sup>32</sup>

The lack of regulatory personnel to perform oversight affected McKesson's personnel's ability to perform their due diligence obligations. Regulatory Affairs Director, Michael Oriente, described in an email dated June 30, 2009, that he was "in the eye of the storm" reviewing threshold change requests from customers at the end of the month which was a busy time for threshold change reviews and determining whether or not they should be granted.<sup>33</sup>

Mr. Gustin became so concerned about the lack of due diligence being conducted by McKesson that he even noted to other colleagues in regulatory affairs that "[w]e as DRAs need to

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<sup>30</sup> P-00097; P-42622

<sup>31</sup> P-13737

<sup>32</sup> 5/25 Trial Tr. (Ashworth) at 219 (Q: Sir...you as a sales rep would not only call and warn the customer they were getting close to the threshold, but you would actually ask the customer if they wanted to increase their threshold. True? You would ask them if they wanted to increase their threshold after your warning. Is that accurate? A: I would, I would ask if they, they needed a threshold change. And if they did, that would start the whole threshold request procedure.).

<sup>33</sup> Trial Tr. May 24, 2021 (Oriente) 140-141; P-13068.

get out visiting more customers and away from our laptops or the company is going to end up paying the price...big time.”<sup>34</sup>

Mr. Oriente emphasized that due diligence is the main function that he serves as a Director of Regulatory Affairs in exercising his responsibility with the CSMP.<sup>35</sup> Mr. Oriente responded,

I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up.<sup>36</sup>

The above measures individually and collectively rendered McKesson’s CSMP ineffective as an anti-diversion tool. Thus, while the CSMP could have been used as a tool to identify suspicious orders and properly investigate them, significant efforts were undertaken by McKesson to thwart the effectiveness of the system as a whole.

**D. MR. RAFALSKI ESTABLISHED THAT MCKESSON FAILED TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION IN HUNTINGTON AND CABELL COUNTY**

Mr. Rafalski is a former Drug Enforcement Agency (“DEA”) diversion investigator with extensive law enforcement experience relating to the distribution of controlled substances under the Controlled Substances Act (“CSA”).<sup>37</sup> Based on this experience, he carefully assessed Defendants’ Suspicious Order Monitoring (“SOM”) programs and testified to their serious flaws with regard to the maintenance of effective controls against diversion.<sup>38</sup> Defendants request that the Court “exclude Mr. Rafalski’s testimony, which they assert would provide “an independent

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<sup>34</sup> P-08763 at 3.

<sup>35</sup> Trial Tr. May 24, 2021 (Oriente) at 146.

<sup>36</sup> P-08763 at 2. Trial Tr. May 24, 2021 (Oriente) at 145-146.

<sup>37</sup> See 5/26 Trial Tr. (Rafalski) at 15-16.

<sup>38</sup> *Id.* at 110-115.

basis for granting judgment under Rule 52(c).<sup>39</sup> Plaintiffs hereby incorporate herein their Response to Defendants' Motion to Exclude Mr. Rafalski's testimony, Doc. No. 1396.

Mr. Rafalski testified regarding six methodologies—two based on an approach endorsed by a United States Court of Appeals, and four based on systems Defendants and other distributors have used—that McKesson could have used to identify suspicious orders (Methods A-F).<sup>40</sup> Applying these to McKesson's customer and due diligence reports, Mr. Rafalski established the numbers of orders Defendants shipped that should have been flagged as "suspicious" under the law and should have triggered due diligence investigations.<sup>41</sup>

This review revealed both the absence of any evidence to dispel the suspicions that were or should have been flagged, and the presence of an absurdly low number of suspicious order reports actually made by McKesson.<sup>42</sup> Applying "Method B" Mr. Rafalski testified that 805,300, or 20.2 percent of the total dosage units for oxycodone and 2,390,800, or 64 percent of the dosage units of hydrocodone sent to Huntington and Cabell County should have been flagged by McKesson as suspicious and not shipped before due diligence was conducted.<sup>43</sup>

Mr. Rafalski also testified that applications of Methods A and C-F would have revealed even higher numbers of suspicious oxycodone and hydrocodone shipments by McKesson.<sup>44</sup>

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<sup>39</sup> Doc. 1439 at 14.

<sup>40</sup> *See id.* at 84-85 (A-D); 93-95 (E-F).

<sup>41</sup> *See id.* at 102 (review of Defendants' due diligence and customer files); *id.* (review of Defendants' suspicious order reporting).

<sup>42</sup> *See id.* at 102; 104-105.

<sup>43</sup> *Id.* at 98.

<sup>44</sup> *See id.* at 97 (Method A – 3,501,970 or 87.9 percent of total dosage units of oxycodone and 3,261,250 or 87.4 percent of total dosage units of hydrocodone); *id.* 98 (Method C – 2,405,620 or 60.4 percent total dosage units of oxycodone and 2,362,420 or 63.3 percent total dosage units of hydrocodone); *id.* at 99-100 (Method D – 1,005,320 or 25.2 percent total dosage units of oxycodone and 1,245,640 or 33.4 percent total dosage units of hydrocodone); *id.* at 100-101 (Method E – 2,098,560 or 52.7 percent of total dosage units of oxycodone and 2,484,640 or 66.6

Mr. Rafalski testified that there was no evidence in the record that McKesson conducted sufficient due diligence of the Rite Aid stores in Cabell-Huntington and other Cabell County customers when increasing thresholds of hydrocodone and oxycodone for those stores.<sup>45</sup> He found no evidence that McKesson was sufficiently monitoring Rite Aid's self-distribution of hydrocodone to its stores in Cabell-Huntington.<sup>46</sup> He further found no evidence that McKesson had conducted an appropriate Level I or Level II review for its retail national account customers in Cabell-Huntington.<sup>47</sup> Mr. Rafalski opined that McKesson did not maintain effective control to prevent diversion of prescription opioids into the illicit market in Cabell-Huntington.<sup>48</sup>

Finally, Mr. Rafalski offers an additional opinion: based on his education, background, experience, and on his review of McKesson's documents and conduct, including those evidencing McKesson's lack of effective controls to prevent diversion and systemic failure to conduct due diligence, that it was more likely than not that flagged orders regarding which McKesson did not conduct due diligence would be diverted.<sup>49</sup>

## **II. MCKESSON FAILED TO PERFORM DUE DILIGENCE ON SUSPICIOUS ORDERS AND SHIPPED ORDERS TO PHARMACY CUSTOMERS WITH KNOWLEDGE THAT THEIR ORDERS WERE SUSPICIOUS**

But even if McKesson had been able to detect suspicious orders, it would have made no difference because its identification of orders as either excessive or suspicious had no bearing on what it decided to ship to its pharmacy customers. While orders appearing on the DU-45 reports

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percent of hydrocodone); and *id.* at 101 (Method F – 3,713,000 or 93.2 percent of total dosage units of oxycodone and 3,648,650 or 97.9 percent of total dosage units of hydrocodone).

<sup>45</sup> *Id.* at 106.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 106-107.

<sup>48</sup> *Id.* at 108.

<sup>49</sup> *Id.* at 108-109, 112-113.

were provided to the DEA, these orders were not investigated or blocked but instead were shipped to the pharmacy customers, regardless of any indicators of suspicion.<sup>50</sup> Similarly, LDMP did not automatically block orders that exceeded the threshold.<sup>51</sup> Without any policy to identify or block suspicious orders, the result is an inevitably inflated number of opioids shipped across the country, including into pharmacies in West Virginia and the Cabell/Huntington. Even when McKesson in theory implemented a due diligence policy, in practice, the first line of due diligence was made by its sales force, which had every incentive to ship as many orders as possible.

Under McKesson's "Know Your Customer" process, McKesson's files show that its due diligence process was very rudimentary in nature and few substantive investigations were performed. The lack of due diligence files makes clear that McKesson was failing to comply with the CSA's investigatory requirements. The failure to document due diligence was also a recurrent problem for Michael Oriente who was responsible for the largest McKesson retail customer in Cabell County – Rite Aid.<sup>52</sup> As an additional example, Level 1 forms completed for Cabell/Huntington pharmacies were not completed properly and didn't contain necessary information for McKesson to properly conduct due diligence.<sup>53</sup>

During the Distributor Initiative meeting in 2005, DEA made clear to McKesson that it needed to be blocking orders it deemed as suspicious.<sup>54</sup> It was not until **three** years later McKesson launched the CSMP in May 2008 that McKesson implemented a system that would

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<sup>50</sup> Hilliard, 1/10/19 Depo at 52:21-53:3.

<sup>51</sup> (Oriente) 5/24 Tr. at 35; Hilliard, 1/10/19 Depo at 63.

<sup>52</sup> 5/24 Trial Tr. (Oriente ) at 184-186, 187-188.

<sup>53</sup> 5/24 Trial Tr. (Ashworth) at 224-226; P-28152.

<sup>54</sup> 6/7 Trial Tr. (Rannazzisi) at 213-215.

systemically block suspicious orders.<sup>55</sup> However, it is clear that the CSMP contained the multiple loopholes noted above that functioned to block as few orders as possible, ensuring that the controls that were put in place remained ineffective.

McKesson routinely increased thresholds without obtaining adequate justifications for the increase. In order to have a threshold increased under the CSMP, a customer was supposed to provide documentation supporting a legitimate change in business that warranted the threshold increase. However, these requirements were consistently ignored. Internally, McKesson recognized the high thresholds that were being permitted by the CSMP. On April 15, 2011, Director of Regulatory Affairs, David Gustin, stated:

We have gotten to the point where certain % of increases are almost automatic and where we are too easily accepting of “reasons” like “business increase” for raising thresholds by small amounts. The SOP says clearly that this is not an acceptable reason unless sales data supports it.<sup>56</sup>

Regulatory Affairs Director Tom McDonald noted that the due diligence to support increased thresholds was insufficient: was also noted in an email dated July 27, 2012:

“I have noticed a trend with TCRs [threshold change requests] that needs to be addressed. The information submitted on the TCR is extremely important to our documentation process. When I screen the CR, I’m assuming some steps have been completed. First and foremost is direct contact with the customer...Be sure you are noting who you spoke with when completing the documentation portion. Ask for a specific reason for the increase in usage. Business growth should be accompanied by specific examples of what is generating that growth...General terms like ‘business growth’ or ‘customer hit their threshold’ are not acceptable...”<sup>57</sup>

### **III. McKesson Failed To Implement The Due Diligence Programs It Adopted**

As described below, McKesson did not apply the due diligence policies at its Washington Courthouse Distribution Center, nor did it apply them to chain pharmacies or local pharmacies.

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<sup>55</sup> Hilliard, 1/10/19 Depo at 97-98; 296-300.

<sup>56</sup> P-12821\_00003.

<sup>57</sup> P-08761.

The limited utility, implementation, and enforcement of McKesson's due diligence programs meant that they were wholly ineffective tools to identify problematic customers, stop suspicious orders, or to prevent diversion. Without an effective or meaningful due diligence program in place, McKesson's opioid shipments remained at relentlessly high levels across the country and in Cabell-Huntington and the surrounding communities.

**A. McKesson Did Not Apply Its Due Diligence Policies to its Washington Courthouse Distribution Center**

Serious deficiencies were also noted during a McKesson internal audit of the Washington Courthouse Distribution Center. According to an email dated April 20, 2011, sent from Donald Walker to Michael Oriente, Dave Gustin, Gary Hilliard, and others, Mr. Walker provided the results of an internal audit focusing on, among other things, consistently following standard operating procedures including documentation.<sup>58</sup> The results of the audit indicated that "the controls related to regulatory compliance, operations, and system access need to be strengthened and enhanced." Further, the audit noted that "certain controls related to DEA, FDA, and state license monitoring are not operating consistently."<sup>59</sup>

The audit report specifically indicated that the Washington Court House Distribution Center, which services Cabell/Huntington, failed to complete or retain threshold change requests forms on file for July and November 2010.<sup>60</sup> Mr. Walker acknowledged that "we have work to do, we need to collectively and collaboratively step up our reinforcement following SOP's and

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<sup>58</sup> P-00115.

<sup>59</sup> Id. at 7.

<sup>60</sup> Id. at 13-14 (The audit also noted that the required Level One forms were not completed for all 19 omits in July 2010, and all 11 omits in November 2010. In addition, the omit report was not signed and dated by DC management as required by the policy).

completing various compliance tasks...”<sup>61</sup>

**B. McKesson Did Not Apply Its Due Diligence Policies to Chain Pharmacies**

McKesson has a long history of providing retail national account customers with absolute deference in granting threshold increase requests. McKesson’s Senior Director of Distribution Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national customers and generally deferred to the customers to decide when it was appropriate for them to obtain threshold increases for controlled substances.<sup>62</sup> This testimony was confirmed with internal McKesson documents.<sup>63</sup> These lax practices resulted in McKesson routinely granting threshold increases to retail national account customers without any apparent due diligence, including many for retail national account customers in Cabell/Huntington.

**C. McKesson Did Not Apply Its Due Diligence Policies to Local Pharmacies**

McKesson’s conduct with respect to Custom Script illustrates its failure to monitor and investigate suspicious orders, specifically as to customers in Cabell County. McKesson increased the oxycodone thresholds for Custom Script three times in four months in 2010, ultimately increasing the oxycodone thresholds from 8,000 dosage units per month to 30,500 dosage units per month.<sup>64</sup> McKesson has produced no due diligence documentation related to any of these threshold increases other than one threshold change report, which is discussed in detail below. In

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<sup>61</sup> P-00115 at 1.

<sup>62</sup> Walker, 10/2/20 Depo at 190-192.

<sup>63</sup> P-42796; P-12743; P-12836.

<sup>64</sup> P-13712.

fact, the only documented diligence done on Custom Script didn't even occur until after the ordering by Custom Script decreased in 2013.<sup>65</sup>

The final threshold increase in 2010 took Custom Script's oxycodone threshold from 23,500 to 30,500 dosage units per month. The only reason provided for this increase by Custom Script was that it expected increased oxycodone sales due to marketing it was conducting targeting local physicians, including pain management physicians.<sup>66</sup> This intent to expand its controlled substance business, especially among pain management physicians demonstrates another red flag that was not investigated by McKesson.<sup>67</sup>

In 2011 alone, Custom Script purchased 159,720 dosage units of oxycodone from McKesson. Mr. Ashworth confirmed this number was above average for a McKesson customer.<sup>68</sup> Transactional data also indicates that Custom Script predominantly purchased oxycodone at the 30mg dose, which is another red flag for potential diversion.<sup>69</sup> There is no evidence that McKesson investigated this red flag.<sup>70</sup>

Further, from May 2011 to March 2012 Custom Script's controlled substance to prescription ratios consistently remained at or above 90%. There is no evidence that this red flag was investigated by McKesson.<sup>71</sup> This is all the more concerning given the testimony from Mr. Oriente that any customer with a 90% control to purchases ratio should automatically be let go as

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<sup>65</sup> P-13284.

<sup>66</sup> P-13714.

<sup>67</sup> 5/24 Trial Tr. (Oriente) at 213-214; P-13284.

<sup>68</sup> 5/25 Trial Tr. (Ashworth) at 251-252.

<sup>69</sup> P-12643.

<sup>70</sup> P-13284; 5/25 Trial Tr. (Ashworth) at 215.

<sup>71</sup> P-13710.

a customer by McKesson.<sup>72</sup> Mr. Ashworth further testified that any controls to overall purchase ratio over 50% is high, and that Custom Script's ratio was over 90% for a period of time.<sup>73</sup>

Two of the pain clinic doctors Custom Script was working with (Dr. Fisher and Dr. Webb) had faced license suspensions, but there is no evidence that McKesson ever investigated this information.<sup>74</sup> In fact, one of the pain management doctors faced a license suspension for improper opioid prescribing years before Custom Script began filling his opioid prescriptions.<sup>75</sup> The other engaged in excessive opioid prescribing, which again was not investigated by McKesson.<sup>76</sup> Thus, this demonstrates that McKesson failed to monitor and investigate suspicious orders placed by its Cabell/Huntington customers.

McKesson ignored its compliance responsibilities completely with respect to Rite Aids in Cabell/Huntington. Notwithstanding the fact that Gary Boggs, Vice President of Regulatory Affairs and Compliance for McKesson, acknowledged that it is improper and a violation of the CSA for a distributor to delegate its CSA duties to its customers,<sup>77</sup> McKesson's national practice was to defer to national accounts to decide when they would get threshold increases.<sup>78</sup> McKesson also admitted that it was never made privy to the specifics of any retail national account customer's SOMs program.<sup>79</sup> There was also a lack of sufficient due diligence as to Cabell Rite Aids.<sup>80</sup>

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<sup>72</sup> 5/24 Trial Tr. (Oriente) at 217.

<sup>73</sup> 5/25 Trial Tr. (Ashworth) at 249-250.

<sup>74</sup> 5/25 Trial Tr. (Ashworth) at 250-251; P-13284.

<sup>75</sup> 6/15 Trial Tr. (Keller) at 122-123, 129-130, 133.

<sup>76</sup> 6/15 Trial Tr. (Keller) at 117-118, 136-137.

<sup>77</sup> Boggs, 1/17/19 Depo at 87-88.

<sup>78</sup> Walker, 1/10/19 Depo at 190-204; P-42796, P-12743, P-12836.

<sup>79</sup> Walker, 1/10/19 Depo at 225-226.

<sup>80</sup> 5/26 Trial Tr. (Rafalski) at 106-107.

McKesson failed to properly monitor Rite Aid's self-distribution of hydrocodone, which prevented it from properly assessing whether any of McKesson's hydrocodone shipments to Rite Aid were suspicious.<sup>81</sup>

Rite Aid thresholds nationally, including in Cabell County, were set too high.<sup>82</sup> Level 1-3 reviews were not being done nationally for retail national accounts, include Rite Aids.<sup>83</sup> Another problem was that automatic threshold increases for opioids were provided to Cabell County Rite Aids.<sup>84</sup> Rite Aid was also provided threshold warning reports that assisted Rite Aid in ensuring its orders would not end up being blocked for exceeding thresholds.<sup>85</sup>

#### **IV. McKesson Distributed Unreasonable Quantities of Opioids to Pharmacies in Cabell-Huntington and the Surrounding Communities**

The evidence shows that McKesson distributed unreasonable quantities of opioids to its customers in Cabell-Huntington and the surrounding communities. The evidence shows this excessive distribution was the direct result of McKesson's failures to detect, investigate, and halt suspicious orders in order to prevent diversion. The excessive quantities of opioids that McKesson distributed to these individual stores were, moreover, clear signs that the opioids McKesson was selling were being diverted there. There quantities were simply too high be used exclusively for legitimate purposes.

For instance, Custom Script Pharmacy, discussed above, is located Barboursville in Cabell County. Barboursville had a 2010 population of 3,964.<sup>86</sup> In the four years period McKesson

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<sup>81</sup> 5/26 Trial Tr. (Rafalski) at 106:12-21; 5/24 Trial Tr. (Oriente) at 225-226.

<sup>82</sup> P-12967.

<sup>83</sup> P-00116, 5/26 Trial Tr. (Rafalski) at 106-107.

<sup>84</sup> 5/24 Trial Tr. (Oriente) at 169-170; P-24727a.

<sup>85</sup> 5/24 Trial Tr. (Oriente) Trial at 123-125.

<sup>86</sup> ECF No. 1433-7.

served Custom Script (2010 to 2013), it shipped to Custom Script 441,000 million doses of oxycodone and hydrocodone (based on ARCOS)—over 111 doses for every man, woman, and child.<sup>87</sup> The four-year total masks the fact that Custom Script's orders from McKesson precipitously declined in 2012 and 2013.<sup>88</sup> In 2011 alone, Custom Script purchased approximately 160,000 dosage units of oxycodone from McKesson, a monthly average of over 13,000 pills. From 2006 to 2014, McKesson's average dosage units of oxycontin shipped to its Cabell/Huntington pharmacies was 4,467.<sup>89</sup> For 2011, the average monthly dosage units of oxycontin shipped to Custom Scripts was over two times its average for all West Virginia pharmacies.<sup>90</sup>

McKesson's Rite Aid shipments were also problematic. McKesson made per-pharmacy monthly oxycodone shipments averaging 4,294 dosage units nationally, 4,559 dosage units in West Virginia, and 4,467 dosage units in Cabell-Huntington.<sup>91</sup> Yet its shipments to the Rite Aid #968 pharmacy store in Huntington averaged 7,552 dosage units per month.<sup>92</sup> This is over 1.5 times McKesson's national, West Virginia, and Cabell/Huntington averages. This difference between McKesson's national shipping average and its Rite Aid #968 average also represents an excess of almost 40,000 dosage units of oxycodone per year that McKesson shipped into Cabell and Huntington.

The Rite Aid sales are even more problematic when one considers that during this time Rite Aid was also self-distributing opioids to its stores. From 2006 to 2014, McKesson shipped

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<sup>87</sup> See 44747\_0002, 44747\_006.

<sup>88</sup> See 44747\_008.

<sup>89</sup> See 43225\_0013.

<sup>90</sup> See 44747\_008.

<sup>91</sup> See 43225\_0013.

<sup>92</sup> *Id.*

a total of 3,239,480 oxycodone and hydrocodone pills to the four Rite Aid pharmacies it serviced.<sup>93</sup> Those totals were in addition to the 5,545,020 dosage units Rite Aid distributed to itself for those pharmacies resulting in 8,784,500 dosage units to these four stores.<sup>94</sup>

In addition, McKesson's sales to pharmacies in nearby counties undoubtably contributed to diversion in Cabell/Huntington. For example, from 2006 to 2014, in nearby Chapmanville, W.Va., a Logan County city 55 miles away with a 2010 population of 1,256, McKesson distributed 823,900 dosage units of OxyContin to Chapmanville Pharmacy, a monthly average of 15,844.<sup>95</sup> The distributions of hydrocodone follow the same pattern. McKesson distributed 5,122,920 dosage units of hydrocodone with a monthly average of 116,4302 to Family Discount Pharmacy, 3,306,110 dosage units of hydrocodone with a monthly average of 63,579 to Chapmanville Pharmacy, and 2,106,860 dosage units of hydrocodone with a monthly average of 40,517 to Man Pharmacy.<sup>96</sup> Logan County's entire population was 32,019 in 2010. McKesson's distributions to those three pharmacies would allow for 329 pills to every Logan County resident.

Finally, in 2006 and 2007, McKesson shipped 4,836,310 hydrocodone pills and 119,400 oxycodone pills to Sav-Rite Pharmacy in Kermit, W.Va., a Mingo County town 96 miles from Huntington, with a population of 406 people.<sup>97</sup> The DEA itself agreed with respect to these shipments by McKesson that there is no conceivable medical need for a town of 400 people to receive almost 5,000,000 opioid pills in two years.<sup>98</sup>

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<sup>93</sup> 44711\_00044.

<sup>94</sup> *Id.*

<sup>95</sup> 43255\_00013

<sup>96</sup> 43255\_00013

<sup>97</sup> Hartle, 8/1/18 Depo at 450-55.

<sup>98</sup> Prevoznik, 4/18/19 30(b)(6) Depo at 605-07.

**V. McKesson Knew that its Anti-Diversion Programs Were Inadequate, and Knew the Devastating Effects of the Failure to Maintain Controls Against Diversion, But Failed to Make Changes**

**A. The DEA Told McKesson About Flaws in Its Program, but McKesson Consistently Ignored this Regulatory Guidance.**

The evidence elicited at trial shows that the DEA communicated specific flaws in McKesson's diversion control programs throughout the years. The DEA's Distributor Initiative Meetings, "Dear Registrant" Letters sent to McKesson, and enforcement actions against McKesson all provided bright line guidance related to McKesson's regulatory obligations and responsibilities to maintain effective controls to prevent diversion. McKesson's response to this guidance was to continue to maximize profits through excessive levels of opioid shipments to its customers. McKesson's failures, over the course of years, to heed the DEA's consistent message about the failures of its diversion control programs demonstrates the unreasonableness of McKesson's conduct with respect to the distribution of opioids.

**1. The DEA Did Not Approve Diversion Control Programs**

McKesson attempts to justify sidestepping the DEA's guidance by arguing the DEA had approved its practice of shipping orders prior to 2008.<sup>99</sup> Plaintiffs' incorporate Plaintiffs' Response to AmerisourceBergen Drug Corporation's Memorandum in Support of Motion for Judgment Under Rule 52(c) Based on Plaintiffs' Failure to Prove Culpable Conduct – Evidence §VI.A.1 which details how the DEA does not approve or endorse diversion control programs.

**2. The 2005 Distributor Initiative Meeting Provided Regulatory Guidance to McKesson that McKesson Ignored**

In 2005, McKesson attended a meeting with the DEA in which the DEA provided specific guidance to McKesson on its regulatory obligations and responsibilities to maintain effective

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<sup>99</sup> See Dkt. 1449 at 19-20.

controls against diversion.<sup>100</sup> During the meeting, DEA made clear to McKesson that it needed to block orders it deemed as suspicious.<sup>101</sup> The DEA expressed to McKesson in 2005, was that it had identified certain McKesson customers who were ordering “substantial quantities” of hydrocodone products.<sup>102</sup> Despite learning of DEA’s concerns, McKesson sold more than two million dosage units of hydrocodone in a period of just 21 days to many of the same pharmacies.<sup>103</sup> The national impact of these types of sales cannot be understated.

Plaintiffs incorporate Plaintiffs’ Response to AmerisourceBergen Drug Corporation’s Memorandum in Support of Motion for Judgment Under Rule 52(c) Based on Plaintiffs’ Failure to Prove Culpable Conduct – Evidence §VI.A.3 in regard to the testimony and content of the DEA’s Distributor Initiative Meetings and PowerPoint presentation.

### **3. The “Dear Registrant” Letters Provided Regulatory Guidance to McKesson that McKesson Ignored**

During 2006 and 2007, the DEA sent three letters to registrants across the country, including McKesson, outlining its legal obligations to conduct due diligence, report suspicious orders, and avoid filling suspicious orders.<sup>104</sup> Plaintiffs incorporate Plaintiffs’ Response to AmerisourceBergen Drug Corporation’s Memorandum in Support of Motion for Judgment Under Rule 52(c) Based on Plaintiffs’ Failure to Prove Culpable Conduct – Evidence §VI.A.4 in regard to the testimony and content of the DEA’s “Dear Registrant” letters.

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<sup>100</sup> See P-12805, 6/7 Trial Tr. (Rannazzisi) at 207.

<sup>101</sup> 6/7 Trial Tr. (Rannazzisi) at 213-215.

<sup>102</sup> P-12805 at 00001.

<sup>103</sup> P-00051

<sup>104</sup> P-00032; 6/8 Trial Tr. (Rannazzisi) at 115-16.

#### 4. **DEA Enforcement Actions Put McKesson on Notice that Its System Was Inadequate to Maintain Effective Controls to Prevent Diversion**

In August 2006, DEA issued an Order to Show Cause to McKesson's Lakeland Distribution Center for violations of the Controlled Substances Act in connection with its sales to internet pharmacies.<sup>105</sup> The Order to Show Cause noted that during the four-month period from October 2005 through January 2006, the average number of hydrocodone tablets purchased nationally and in Florida was approximately 24,000 tablets per pharmacy. Yet, during that same four-month period, McKesson shipped quantities of hydrocodone tablets to seven internet pharmacies well in excess of that average. For example, McKesson shipped a total of 3.5 million hydrocodone pills to one of these pharmacies – an amount that was **nearly 150 times more** than the national average.<sup>106</sup> The violations were not unique to McKesson's Lakeland facility. On November 1, 2007, the DEA issued a second Order to Show Cause to McKesson's Landover, Maryland distribution facility.<sup>107</sup> At the same time, at least four other distribution centers were also under investigation by the DEA.<sup>108</sup> Thus, McKesson's failure to maintain controls against diversion contributed to this wide-scale diversion of opioids occurring through internet pharmacies and spreading across the country and all states.<sup>109</sup>

McKesson's 2008 Memorandum of Agreement with the DEA confirms its lack of CSA compliance. On May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement ("2008 Agreement") with the DEA and paid \$13,250,000 in fines for its failure to

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<sup>105</sup> P-23733; P-00016

<sup>106</sup> P-00016.

<sup>107</sup> P-00016 at 00188; 00202

<sup>108</sup> P-00016 at 00188; 00202

<sup>109</sup> 6/7 Trial Tr. (Rannazzisi) at 191-92.

maintain controls against diversion and to report suspicious orders. The 2008 Agreement specifically addressed conduct at six distribution centers, but the agreement’s “Covered Conduct” applied to all McKesson DEA registered facilities based on the company’s failure to maintain adequate controls against diversion on or prior to December 31, 2007 at “all distribution facilities operated, owned, or controlled by it”, including its failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b), on or before December 31, 2007.”<sup>110</sup> McKesson’s internal documents acknowledged that the fine could have been as high as \$46 million given the multiple distribution centers under investigation, the over 4,600 violations identified by the DEA, and McKesson’s shipment of millions of dosages to pharmacies that were later indicted.<sup>111</sup>

**5. Letters from the DOJ/DEA Put McKesson on Notice that Its Systems Were Inadequate to Maintain Effective Controls to Prevent Diversion**

In a clear signal that McKesson’s anti-diversion programs failed to maintain effective controls to prevent diversion, DOJ/DEA letters from 2013 and 2014 further confirmed and put McKesson on notice of numerous failures of its CSMP from 2008-2013.<sup>112</sup>

**B. McKesson Was Aware of the Devastating Consequences that its Failure to Maintain Effective Controls Against Diversion Would Have on Communities Like Cabell/Huntington.**

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<sup>110</sup> P-00016 at 00189.

<sup>111</sup> P-00011 at 3.

<sup>112</sup> See P-00122 at 2 (November 14, 2014 letter from Dana Hill, DEA Office of Chief Counsel, Diversion and Regulatory Division, to McKesson noting that “McKesson’s systemic failures” were also evident at WCH DC, noting that McKesson did not report any orders as suspicious after the 2008 settlement; McKesson failed to “instill a culture of compliance”; and “WCH’s blind eye for suspicious ordering was again apparent when it set a monthly threshold of 112,000 dosage units of hydrocodone products for a pharmacy in Mount, Gay, West Virginia, with an adult population of less than 1,500”); P-00118 (Nov. 6, 2013, Letter from Assistant US Attorney Alan McGonigal to McKesson indicating that the US Attorney’s Office became aware of dozens, if not hundreds of suspicious orders being filled by McKesson for a small family pharmacy, Judy’s Drug Store, in Grant County, West Virginia. Noting that no SOR’s for the pharmacy were provided to

McKesson has also been well aware of the problems of opioid abuse and diversion and the ongoing opioid epidemic for years, further demonstrating the unreasonableness of its conduct. The members of McKesson's diversion control team were aware of the opioid crisis, opioid addiction, the relationship between pain pills and heroin. McKesson admitted the following:

- Distributors “are a force-multiplier” and that “[w]ithout sustained sources of supply major diversion schemes wither away;<sup>113</sup>
- One of the foreseeable harms of engaging in unlawful conduct in the distribution of prescription opioids can be diversion;<sup>114</sup>
- The prescription opiate epidemic is a hazard to public health and safety;<sup>115</sup>
- That the DEA informed Distributors that wholesale distributors who supply pharmacies without appropriate due diligence have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted and pose an imminent threat to the public health and safety;<sup>116</sup>
- People were dying of narcotics overdoses;<sup>117</sup>

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the DEA); P-00119 (March 20, 2014, Letter from US Attorney William Ihlenfeld that: “I cannot accept that the CSMP implemented by McKesson after the 2008 settlement was designed to identify suspicious customers. It is my informed belief that such a contention is more rationalization than reality.”); P-00121 (Aug. 13, 2014 Letter from US Attorney Amanda Rocque to McKesson regarding violations at McKesson-Aurora Distribution Center, noting that “McKesson-Aurora made a calculated business decision to avoid reporting suspicious orders. Recognizing that the failure to report suspicious orders is egregious for two reasons: 1) what the law mandates is minimal and easily accomplished; 2) McKesson Aurora “should have known better” in light of the 2008 agreement where McKesson paid \$13,250,000. McKesson designed a compliance system and McKesson-Aurora “immediately set its mind to disabling the system”). The admissibility of these letters is subject to motion practice. *See* Doc. 1436.

<sup>113</sup> P-00002 at 000046; *see also* Hartle Depo, 7/31/18 at 297:2-298:5 (“distributors have great power,” and McKesson had a duty to “control the supply to downstream customers”)

<sup>114</sup> Hartle, 7/31/18 Depo at 364-366.

<sup>115</sup> Hartle, 7/31/18 Depo at 364-366.

<sup>116</sup> P-12814 at 00005 (quoting then-DEA Deputy Assistant Administrator Joseph Rannazzisi).

<sup>117</sup> Gustin, 8/17/18 Depo at 40.

- There was a direct correlation between the misuse of prescription opioids and the skyrocketing incidences of heroin use in communities all across the United States;<sup>118</sup>
- There was an uncaring indifference to those who transitioned from McKesson's opioids to illegal drugs;<sup>119</sup> and
- The impact of effective compliance and the disastrous effects that can occur when check and balances collapse.<sup>120</sup>

Thus, McKesson's was aware of the devastating effects of its failure to maintain effective controls against diversion would have on communities like Cabell/Huntington.

#### **VI. THE EVIDENCE SHOWS THAT MCKESSON'S DISTRIBUTION OF OPIOIDS INTO CABELL-HUNTINGTON VIOLATED THE CSA AND THE REQUIREMENT THAT MCKESSON PROVIDE "EFFECTIVE CONTROLS" AGAINST DIVERSION**

The CSA requires distributors like McKesson to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty").<sup>121</sup> The CSA defines

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<sup>118</sup> *Id.* at 00008 ( "the number of people who have used heroin in the past year has been steadily increasing approximately 50 percent since 2008," that "injection drug users report prescription opioid use predates heroin use and motivates them to try heroin"; and that "users turn to heroin because it is cheaper and/or easier to obtain than prescription opioids."); Hartle, Nathan 07-31-2018 (320:14 – 321:10) ("the abuse of prescription opioid pills is a gateway to the initiation of heroin").

<sup>119</sup> P-16690 ("Good...let them move to heroin and meth...we don't have to monitor that.")

<sup>120</sup> P-16210 (demonstrating that the impact from failure of compliance systems can be as devastating as a building collapsing).

<sup>121</sup> *See* 21 C.F.R. § 1301.74; *In re Nat'l Prescription Opiate Litig.*, 1:17-md-02804-DAP, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007).

suspicious orders to include “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>122</sup> McKesson asserts that its pre-2008 system “complied with contemporaneous DEA guidance and prevailing industry standards,”<sup>123</sup> As set forth in Plaintiffs’ Response to AmerisourceBergen Drug Corporation’s Memorandum in Support of Motion for Judgment Under Rule 52(c) Argument § II.C (Dkt 1471), which Plaintiffs incorporate herein, compliance with the requirements in the Controlled Substances Act has always been the law.

The evidence shows that McKesson shipped suspicious orders of opioid products without conducting due diligence. As discussed above, until 2008, McKesson relied on excessive order reports to identify and report excessive orders. These excessive orders reports were generated after the orders had already been shipped. The generation of these after-the-fact reports made it impossible for McKesson to comply with the no-shipping duty. Because the identified orders had already been shipped to their respective customers, it would have been impossible to conduct any due diligence on the orders identified on the excessive order reports prior to shipping.

Notwithstanding the fact that McKesson did not have a policy to stop shipment of suspicious orders until 2008. For the reasons set forth herein and in AmerisourceBergen Drug Corporation’s Memorandum in Support of Motion for Judgment Under Rule 52(c), Argument § II.C., compliance with requirements of the Controlled Substances Act has always been the law. McKesson set artificially high thresholds, continually shipped orders in excess of thresholds, failed to conduct due diligence and failed to maintain documentation that it conducted due diligence. As noted above, McKesson set artificially high thresholds, increased those thresholds without

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<sup>122</sup> 21 C.F.R. § 1301.74(b).

<sup>123</sup> Doc. 1439 at pp. 16-17.

adequate due diligence, and otherwise assisted customers in circumventing their thresholds. McKesson asserts that the “industry practice” permitted the use of such reports.<sup>124</sup>

Additionally, McKesson violated its duty to report under the CSA. McKesson systematically failed to report suspicious controlled substance orders nationally and specifically in Cabell County. As part of the \$150 million dollar 2017 settlement with DEA McKesson accepted responsibility for this national failure to “identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner consistent with the 2008 settlement.”<sup>125</sup> The conduct involved spanned from 2009 to 2017.<sup>126</sup>

Further, as Plaintiffs’ expert James Rafalski testified, there is zero evidence of any specific orders being reported by McKesson to DEA related to Cabell County customers from 1996 to 2012.<sup>127</sup> This finding is corroborated by multiple other pieces of evidence. For example, in 2011 McKesson’s Washington Courthouse Distribution Center failed a DEA audit for various reasons, including failing to properly report suspicious orders to DEA.<sup>128</sup> McKesson’s own suspicious order report produced in this case also makes clear that McKesson reported no suspicious orders from the onset of the report in 2004 until August 2013.<sup>129</sup> The systematic failure to report suspicious orders was further confirmed by an internal McKesson analysis in late 2015 that confirmed that company was still failing to report approximately 1,500 suspicious controlled substance orders monthly.<sup>130</sup>

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<sup>124</sup> Doc. 1439 at 16-17.

<sup>125</sup> P-42554 at 3.

<sup>126</sup> Id.

<sup>127</sup> 5/26 Trial Tr. (Rafalski) at 105-21.

<sup>128</sup> P-42814.

<sup>129</sup> P-42089.

<sup>130</sup> P-13296.

This systematic failure to report suspicious orders is not a mere technical violation. There is also ample record evidence demonstrating that McKesson's systematic failure to report suspicious orders contributed to diversion. As McKesson's own Senior Director of Regulatory Affairs, Nathan Hartle, readily acknowledged reporting suspicious orders plays an important role in preventing diversion.<sup>131</sup> During trial, Joseph Rannazzisi also made clear that when suspicious orders were reported to DEA the agency investigated those orders in an attempt to prevent diversion.<sup>132</sup> Thus, in failing to report suspicious orders on a national basis, and in Cabell County specifically, McKesson deprived the DEA of any ability to investigate the suspicious orders McKesson was receiving as part of its charge to prevent diversion.

## ARGUMENT

### I. UNREASONABLE INTERFERENCE WITH A PUBLIC RIGHT CONSTITUTES A PUBLIC NUISANCE.

West Virginia has adopted the definition of "public nuisance" set forth in § 821B of the Restatement (Second) of Torts ("Restatement"):<sup>133</sup> "A public nuisance is an unreasonable interference with a right common to the general public."<sup>134</sup> Thus, in West Virginia, the touchstone of public nuisance liability is unreasonableness.<sup>135</sup>

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<sup>131</sup> Hartle, 8/1/18 Depo at 76-77.

<sup>132</sup> 6/7 Trial Tr. (Rannazzisi) at 215-216; 219-220; 227.

<sup>133</sup> See *Duff v. Morgantown Energy Assocs. (M.E.A.)*, 421 S.E.2d 253, 257 n.6 (W. Va. 1992); *Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 620 (W. Va. 1985); *State ex rel. Morrissey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021, at \*9 (W. Va. Cir. Ct. Dec. 12, 2014); *Rhodes v. E.I. du Pont de Nemours and Company*, 657 F.Supp.2d 751, 768 (S.D. W.Va. 2009); *Barker v. Naik*, No. 2:17-CV-04387, 2018 WL 3824376, at \*3 (S.D.W. Va. Aug. 10, 2018) (Johnston, C.J.); see also *Callihan v. Surnaik Holdings of WV, LLC*, No. 2:17-CV-04386, 2018 WL 6313012, at \*5 (S.D.W. Va. Dec. 3, 2018).

<sup>134</sup> RESTATEMENT § 821B(1) (1979).

<sup>135</sup> See, e.g., *Duff*, 421 S.E.2d at 262 (reasonableness of conduct determines whether conduct constitutes a nuisance); *West v. National Mines Corp.*, 285 S.E.2d 670 (W. Va. 1981), *reh'g on appeal*, 336 S.E.2d 190 (W. Va. 1985) (activity must be reasonable to avoid liability for nuisance).

Both this Court and McKesson recognize that unreasonableness is the applicable standard. This Court so held in its Memorandum Opinion and Order denying Defendants’ motion for summary judgment regarding fault.<sup>136</sup> For the purposes of this motion, McKesson has conceded that unreasonableness is the standard based on this ruling.<sup>137</sup> As set forth in detail above, the evidence at trial establishes that Plaintiffs have met this burden.<sup>138</sup>

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<sup>136</sup> See April 29, 2021 Memorandum Opinion and Order, Dkt. 1294 at 6 (finding “Defendants have not established that there is a ‘fault’ element (in the way they describe it [intent, recklessness, or negligence]) of a public nuisance claim under West Virginia law.”); *id.* (“The court agrees with plaintiffs that because defendants’ motion does not establish the reasonableness of defendants’ conduct, the motion should be denied.”).

<sup>137</sup> Doc. 1449 at 5. For the purposes of this motion, McKesson also concedes that proof of illegal conduct is sufficient. *Id.* (“for purposes of this brief, McKesson assumes *arguendo* that the standard for “actionable” conduct is *unlawful* or otherwise unreasonable conduct” (emphasis)).

<sup>138</sup> Even assuming *arguendo* that the Defendants are correct that an element of “fault” is required to prove the unreasonableness of their conduct, Dkt. 1449 at 5, n1, the Plaintiffs have met the requirement as Defendants’ conduct was intentional. In denying the Defendants’ motions for summary judgment pertaining to fault, this Court held that “even assuming that there is a culpability (“fault”) element in the public nuisance context, the motion should still be denied because there are disputed issues of material fact about whether defendants’ conduct was intentional.” Dkt. 1294 at 6. As the Court noted, Plaintiffs are not required to prove *mens rea* – or intent to create the opioid crisis or the resulting harms – only that their actions were intentional. Dkt. 1294 at 5-6. Here, the Plaintiffs proved that McKesson’s conduct was an unreasonable interference based on its intentional selling and shipment of high volumes of opioids into Cabell-Huntington.

## **II. Plaintiffs Have Proven that McKesson Unreasonably Interfered with Public Rights**

As described above, the evidence shows that McKesson's conduct was unreasonable in multiple ways. The conduct in question is the distribution of dangerously addictive narcotics with a high risk of diversion. Distributors like McKesson are uniquely able to act to prevent diversion because they know the quantity of opioids they are shipping to their customers within a particular region and can observe patterns of excessive or unusual ordering indicative of diversion at the pharmacies they supply. Nonetheless, McKesson acted unreasonably in failing to control the supply of opioids into Cabell-Huntington and failing to take reasonable steps to prevent diversion of these dangerous drugs.

McKesson acted unreasonably when it distributed an unreasonable quantity of opioids to its retail and chain pharmacies in and surrounding Cabell/Huntington without account of the size of the population of the area into which these drugs were shipped and the scourge of addiction that emerged. It also acted unreasonably in operating its SOM programs: first, because the programs were not designed to detect suspicious orders at risk of being diverted; second, because the programs did not prevent McKesson from shipping orders it knew to be at risk of diversion; third because McKesson did not follow the programs it adopted, and fourth because McKesson knew about the harm its excessive shipments was causing and was repeatedly told what it needed to do in order to operate a proper SOMs program, but repeatedly failed to heed the guidance it was given. Finally, McKesson acted unreasonably with respect to the distribution of opioids when it failed to comply with the requirements of the CSA.

**A. The Volume of Pills Shipped to Pharmacy Customers in and Around Cabell and Huntington Proves Unreasonable Conduct.**

McKesson's distribution of an extraordinarily disproportionate quantity of opioids to pharmacy customers in and around Cabell-Huntington and the surrounding communities was unreasonable.<sup>139</sup> Despite McKesson's diversion control team's knowledge of the opioid crisis, opioid addiction, and the relationship between pain pills and heroin, McKesson distributed increasingly large amounts of opioids into Cabell-Huntington and the surrounding areas.<sup>140</sup>

The vast volume of opioids McKesson supplied to certain pharmacies in Huntington and Cabell County and surrounding areas should have put it on notice that it was not supplying a legitimate market for the drugs.<sup>141</sup> Yet, though Mr. Rannazzisi testified – and common sense dictates – that distributors should consider the volume of opioids it sells to a customer or area relative to its population, McKesson did not weigh these factors in assessing whether orders were suspicious or diversion might be occurring.<sup>142</sup>

It was not only the overall volume of opioids McKesson shipped to Cabell-Huntington and the surrounding communities, but the volume they sold to particular pharmacies that could only have been regarded as pill mills that should have alerted McKesson that they were fueling

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<sup>139</sup> See The Evidence, § IV, *supra*.

<sup>140</sup> See *supra* Evidence §A.4, B.

<sup>141</sup> Plaintiffs incorporate Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation §II.B.1 (Foreseeability of Diversion) (Dkt. 1469).

<sup>142</sup> 6/8 Trial Tr. (Rannazzisi) at 186 ("what we asked them to do is look at your suspicious – your pharmacy population, your customer population, identify anomalies within that population, ordering patterns, and then do your due diligence and see why those anomalies exist"); 5/17 Trial Tr. (Mays) at 203, 205 (between 2007 and 2014 the diversion control program did not rely on populations); Prevoznik, 5/17/19 Depo at 974 (DEA had said that knowledge of a geographic area's problem with controlled substance abuse is a factor that should be taken into account by registrants); see also See 5/26/21 Trial Tr. (Rafalski) at 112 (orders the Defendants knew or should have known were suspicious were likely to be diverted into the illicit market).

diversion.

The figures provided above actually undercount the volume of opioids that reached Huntington and Cabell County. As detailed by James Rafalski, an additional wave of opioids were making their way into West Virginia from Florida and other states via a route often referred to as the “Oxy Express” or “Blue Highway.”<sup>143</sup>

McKesson’s failure to maintain effective controls against diversion, as demonstrated by its failure to conduct due diligence and practice of unjustifiably raising thresholds resulted in an onslaught of pills to particular pharmacies in Cabell-Huntington and the surrounding communities.<sup>144</sup>

**B. The Evidence Relating to McKesson’s Diversion Control Program Establishes Unreasonable Conduct.**

As discussed in detail above, key deficiencies marred each of McKesson’s diversion control programs. McKesson’s diversion control programs were carried out nationally, through centralized compliance staff.

As detailed above,<sup>145</sup> McKesson’s programs for detecting “suspicious orders” of prescription opioids were not designed to, and could not, detect a significant percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion. McKesson depended on monthly, volume-based thresholds for pharmacy customers as triggers for identifying excessive orders. By the time McKesson put thresholds in place, opioid sales and, thus, customer purchasing baselines had already been inflated by nearly a decade of diversion and

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<sup>143</sup> 5/27 Trial Tr. (Rafalski) at 151-152 (“people that would get on airplanes in Huntington and fly to Florida to go to the pain clinics to get pills and then come back”; “Allegiant flight that was – they called it the Pill Express”); Boggs, 1/17/19 Depo at 114-15.

<sup>144</sup> See The Evidence, §§ I, II, III, *supra*.

<sup>145</sup> See The Evidence, § I, *supra*.

excessive sales. Therefore, they were set too high, and offered no meaningful brake on suspicious orders.

McKesson failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed indicia of diversion.<sup>146</sup>

McKesson failed to properly implement the suspicious order monitoring (SOMs) program that it did have. As discussed in detail above, McKesson knew that its SOMs programs were inadequate, and knew the devastating effects of the failure to maintain controls against diversion but failed to make changes to address the inadequacies.<sup>147</sup>

Finally, Mr. Rafalski testified that McKesson's systemic failures to maintain effective controls were a substantial factor in the diversion of prescription opioids into Cabell-Huntington.<sup>148</sup> He further testified that the orders McKesson knew or should have known were suspicious were likely to be diverted into Cabell-Huntington.<sup>149</sup>

### **C. MCKESSON'S CONDUCT WAS UNREASONABLE BECAUSE IT VIOLATED THE CSA**

For the purposes of this motion, McKesson conceded that unlawful conduct meets the unreasonableness standard for culpability for a public nuisance claim in West Virginia.<sup>150</sup>

The undisputed record evidence demonstrates that McKesson has always been aware that its legal duties as a registrant under the CSA include the responsibility to maintain effective

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<sup>146</sup> See The Evidence, § II, *supra*.

<sup>147</sup> See The Evidence, § V, *supra*.

<sup>148</sup> See The Evidence, § I.D, *supra*.

<sup>149</sup> See The Evidence, § I.D, *supra*.

<sup>150</sup> Doc. 1449 at p. 5.

controls against diversion by – at a minimum – (1) designing and implementing a system that identified, reported, and stopped the shipment of suspicious orders and (2) conducting meaningful due diligence on both new and existing customers.<sup>151</sup> The record evidence also shows that although McKesson understood that failing to comply with its regulatory obligations would have devastating consequences for communities like Cabell/Huntington, it did so anyways. Although McKesson developed supposedly “improved” national compliance policies on at least three occasions (and always in response to enforcement activity by the DEA), its actual regulatory compliance remained systemically deficient. These deficiencies affected Cabell/Huntington both directly and indirectly.

The evidence presented at trial and outlined throughout this brief establishes that McKesson violated the CSA and WV CSA. The volume of opioids shipped by McKesson, the lack of controls to identify and stop suspicious orders, and their intentional disregard of what few procedures they had to protect the public each clearly establish statutory and regulatory violations. Such violations of the law are sufficient to allow the Court to conclude that McKesson acted unreasonably.

As demonstrated at trial<sup>152</sup>, each iteration of McKesson’s suspicious order monitoring programs, which were always developed in response to DEA enforcement activity against McKesson, were uniformly implemented across all of McKesson’s distribution centers and failed to provide effective controls against diversion. Although McKesson asserts that it “all times complied with DEA’s evolving expectations for the wholesale drug distributor industry,”<sup>153</sup> the

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<sup>151</sup> Hartle Depo, 7/31/2018 at 85-92.

<sup>152</sup> See The Evidence, § I, *supra*.

<sup>153</sup> McKesson’s Rule 52(c) motion at pp.1-2.

evidence establishes that McKesson failed to maintain any meaningful controls against diversion in its distribution of dangerously addictive opioids. McKesson's diversion control programs and its implementation of such programs, regardless of iteration, violated the requirements of the CSA.

### **CONCLUSION**

For all of the reasons set forth herein, this Court should deny McKesson's Motion for Judgement under Rule 52(c).

Dated: July 25, 2021

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**CERTIFICATE OF SERVICE**

I certify that on July 25, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Anthony J. Majestro